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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

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KEIL & WEINKAUF  
1350 CONNECTICUT AVENUE, N.W.  
WASHINGTON, DC 20036

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/873,431	KOLTER ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
AU 1615

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1615

### **DETAILED ACTION**

Examiner acknowledges receipt of terminal disclaimer, amendment and remarks filed 08/11/04. Claims 1-23, 25 and 26 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, because the specification failed to enable a PVP having a molecular weight of 10,000,000 is withdrawn in light of the amendment to claim in which the enabled molecular weight is recited.
2. The rejection of claims 10 and 14-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in part in light of the amendment to claim 10.

It is however necessary to bring the following to applicants' attention:

Claim 15 still has the "such as" in line 3 after essentially of, and this may be a typographical error that may be corrected.

Claim 14 may be placed in proper Markush by inserting ---selected from --- after "are" in line 3.

Claim 16 may be placed in proper Markush by inserting ---consisting--- after "group" in line 2.

Claim 20 may be placed in proper Markush by inserting ---consisting--- after "group" in line 2.

3. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1615

Claim 26 is vague and indefinite. Claim 26 depends of claim 17. Claim 17 is a dosage form. It is unclear what claim 26 is attempting to do. Claim 26 starts out as a process claim but there is no active step in the process by which the release of active agents may be delayed. The recitation of "the improvement wherein the dosage form is that of claim 17" appears not to be related to the first part of claim 26 and there is steps to show how the improvement is done. Claim 26 is not included in the art rejection because it is not to the Examiner what the claim is intending to accomplish.

***Claim Rejections - 35 USC § 102***

4. The rejection of claims 17-25 under 35 U.S.C. 102(b) as being anticipated by Goertz et al. (US 4,801,460) is withdrawn because applicants' argument that Goertz discloses a copolymer of Vinylpyrrolidone and Vinyl acetate while in the instant claims, a mixture of vinylpyrrolidone and vinyl acetate is used is persuasive.

5. Claims 17-23 and 25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ortega (US 4,837,032).

Applicants argue that in the instant case, PVP is finely dispersed in polyvinyl acetate and in Ortega, the mixture of PVP and PVAc is a physical mixture and therefore, applicants' resultant granules must have a different structure compared with the granules of Ortega where the mixture is a physical mixture. Applicants conclude that it is because of this difference that 70-76% of the active substance is released after 6 hours and 90% released after 8 hours while in the instant case, 40% is released after 6-8 hours.

6. Applicants' arguments filed 08/11/04 have been fully considered but they are not persuasive.

Art Unit: 1615

7. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., PVP finely dispersed in PVAc) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, how a composition is formed has no patentable weight on a composition claim except that process introduces a structural difference from that which is formed by a different method. Also, a physical mixture versus a mixture that has a dispersion of one in another ---- the difference is not immediately clear. Do applicants imply a chemical reaction between the vinylpyrrolidone and vinyl acetate; and is a chemical interaction is contemplated, then a copolymer cannot be ruled out from the formulated mixture of the instant claims. Because, the dispersion of PVP in PVAc is not recited in the instant claims, the granules of Ortega do not differ from the instant granules.

***Claim Rejections - 35 USC § 103***

8. Claims 1-7 and 9-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032).

Applicants argue that Ortega's process is wet granulation process because there is no indication in Ortega that the formulated mixtures might be used in a process that is not a wet granulation.

9. Applicants' arguments filed 8/11/04 have been fully considered but they are not persuasive.

Art Unit: 1615

The argument relies upon limitation that is not claimed and the instant claims do not exclude wet granulation or include wet granulation.

10. Claims 1 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (US 4,837,032) in view of Noda et al. (US 5,389,380).

Applicants argue that the excipients disclosed by Noda considered in combination with Ortega's teaching would not lead the skilled artisan to the claimed process and product.

11. Applicants' arguments filed 08/11/04 have been fully considered but they are not persuasive.

Noda is relied upon for a teaching that theophylline can be combined with lactose or starch or mannitol and because there is a prior art teaching where theophylline is combined with lactose or mannitol or starch, the skilled artisan would expect that theophylline could be successfully composed with those excipients in light of Noda.

### ***Double Patenting***

The rejection of claims 1, 4, 6-23 and 25 under the judicially created doctrine of obviousness-type double patenting is withdrawn because applicants have filed a Terminal Disclaimer.

No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1615

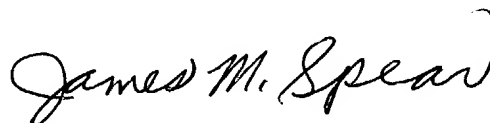
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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